DEPARTMENT OF HEALTH AND HUMAN SERVICES

93180

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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WARNING LETTER

CIN-03-15775

November 19, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Phil Henson
Pinson's Fitness Products
3846 Montgomery Road
Cincinnati, OH 45212

Dear Mr. Henson:

This letter is written in reference to your firm's marketing of the products Pharmalogic XRX Intra-Oral (nasal) Androgenix Spray, Primavar SCC Sublingual Tablets, Test-4-Blast, Deca Derm, and Dermadrol, each of which contains androstenedione and/or androstenediol. Your Internet web site, http://www.pinsonsfitness.com, from which these products may be ordered, states, for example, in the section entitled "Frequently Asked Questions What is Androstenedione?," "...Androstenedione...elevate blood levels of testosterone...potent muscle and strength building capabilities...heightened sexual arousal and function...".

Test-4-Blast, Deca Derm and Dermadrol are topically applied for transdermal absorption to achieve their intended effect. Primavar SCC Sublingual Tablets and Pharmalogic XRX Intra-Oral (nasal) Androgenix Spray are sublingual or intranasal products. These products cannot be dietary supplements because they are not intended for ingestion since they are topical, sublingual or intra-nasal products that are intended to bypass the alimentary canal by direct absorption through the skin, oral or nasal mucosa. The Act defines the term, "dietary supplement" in Section 201(ff)(2)(A)(i) to mean a product that is "...intended for ingestion...". Consequently, a product that is not intended for ingestion cannot meet the definition of "dietary supplement".

Based on their intended uses, to affect the structure or any function of the body of man, these products are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). As drugs, the labeling claims made for these products subject them to the requirements for new drugs [Section 201(p) of the Act] because there is no evidence that these products are generally recognized as safe and effective for their claimed uses. Further, all transdermal drug delivery products are new drugs because of the newness of the dosage or the method or duration of administration or application suggested in the labeling (See Title 21 of the Code of Federal Regulations, Part 310.3). Under Section 505 of the Act, a "new drug" may not be introduced or delivered for introduction into interstate

commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Because your products are not the subjects of approved NDA's, they may not be marketed in the United States and their continued distribution violates Section 505 of the Act.

This letter is not intended to be an all-inclusive review of your Internet web site nor all labeling and products your firm markets. The violation described above is not intended to be an all inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm, including other products containing androstenedione and/or androstenediol, are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be implemented.

Address your reply to the attention of Charles S. Price, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

Mary S. Womack

Mary S. Womack
Acting district Director
Cincinnati District Office